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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,161	08/24/2001	Richard W. Voellmy		4118

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,161

Applicant(s)

VOELLMY, RICHARD W.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 31 March 2005.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

The instantly claimed invention consists of the method step of applying to the scalp or other region susceptible to chemotherapy-induced alopecia of a patient an effective amount of heat. In the view of the examiner, a situation where a patient walks outdoors on a warm and sunny day for up to two hours before going to receive chemotherapy treatment would read on the instantly claimed invention. That hypothetical scenario aside, to ask a patient to sit through at least fifteen minutes and up to two hours of heat treatment at a level that simulates a condition that potentially ranges from a moderate fever to a temperature sufficient to trigger heatstroke would be to place an intolerable burden on that patient.

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Claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides methods for protecting a human patient or a mammalian animal to be subjected to chemotherapy treatment of a tumor not residing in the scalp of the patient or the skin of the animal against chemotherapy-induced alopecia, comprising applying to the scalp

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or other region susceptible to chemotherapy-induced alopecia of a patient an effective amount of heat.

(2) The state of the prior art

Although various methods of preventing and treating chemotherapy-induced alopecia are known in the prior art, by the applicant's own disclosure, the success of such techniques are greatly influenced by a number of factors, including the gender of the patient, the half-life of the chemotherapy agent, and whether the chemotherapy treatment includes only one agent or a combination of agents. Disadvantages of the methods of the prior art include the toxicity imparted by the treatments, patient discomfort, and the administration of therapeutic compounds weeks prior to chemotherapy. Furthermore, by the applicant's own disclosure, relatively little research has been conducted to identify the actual mechanisms of chemotherapy-induced alopecia.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the art is high. In methods of treating a condition, a time-dependence factor must be taken into account. In methods of preventing a condition, the time-dependence factor cannot be easily predicted. Furthermore, as the Background section of the

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Jimenez et al. patent (previously cited in a prior art rejection) reveals, therapeutic agents must be tested for effectiveness against specific, individual chemotherapy agents.

(5) The breadth of the claims

The claims are very broad. The methods claims primarily require the application of heat to the scalp of a subject, with the heat being administered at a sufficient length of time before the administration of a chemotherapeutic drug.

(6) The amount of direction or guidance presented

In the instant specification, the applicant has disclosed that parameters, such as the amount of time the treatment is to be administered before chemotherapy and hair density before and after chemotherapy during clinical studies, help determine the intensity and duration of heat applied to a patient. Furthermore, the applicant has disclosed that such treatment parameters are to be determined empirically, using various methods, including animal modeling. In the view of the examiner, this is interpreted to say that such treatment parameters cannot be predicted or roughly estimated without conducting such testing.

(7) The presence or absence of working examples

Although the applicant has disclosed experimental procedures in detail, actual experimental results do not appear to be provided by the applicant himself. Much of the discussion of the use of a physical inducer of a stress protein response in the instant specification

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takes place in the future tense or in hypothetical or theoretical terms, sometimes based on the research of others in the art.

(8) The quantity of experimentation necessary

Since the treatment parameters, especially with respect to the type and amount of therapeutic agent to be used, cannot be predicted *a priori* but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine proper dosage amounts of heat, in terms of intensity and duration, to be used to treat a patient being administered a particular chemotherapeutic agent, as well as to determine the length of time between the administration of the treatment and the start of chemotherapy.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 16-20 and 23-25 under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* is rendered moot with the cancellation of those claims.

Response to Arguments

Applicant's arguments filed 31 March 2005 have been fully considered but they are considered moot in view of the new grounds of rejection presented above.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
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sj0


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